

Appl. No. 10/633/965
Atty. Docket No. 9152R
Response. Dated: June 9, 2004
Reply to Office Action of March 9, 2004
Customer No. 27752

REMARKS

Claims 1-43 are pending in the present invention. No additional claims fee is believed to be due.

No amendments have been made herein.

Rejection Under 35 USC § 101

The Office Action states that claims 1-23 are provisionally rejected based on copending Application Serial No. 10/368,514. The Office Action further states that claims 24-43 are provisionally rejected based on copending Application Serial No. 10/369,039. Applicant respectfully submits that copending Application Serial No. 10/368,514 and Application Serial No. 10/369,039 have been expressly abandoned. As such Applicant respectfully traverses this rejection as being now moot.

Rejection Under 35 USC § 103

The Office Action states that claims 1-43 are rejected under 35 USC § 103 over a combination of Marlett *et al.*, U.S. Patent No. 6,287,609 (herein referred to as "Marlett") and Nakamura *et al.* U.S. Patent No. 6,045,847 (herein referred to as "Nakamura") or Colliopoulos U.S. Patent No. 5,009,916 (herein referred to as "Colliopoulos"). Applicants respectfully traverse this rejection and assert that there is no teaching, motivation, or suggestion to combine the cited references in view of the current invention. Indeed, Applicants respectfully assert that the Examiner has failed to present a *prima facie* case of obviousness in view of the lack of such teaching, motivation, or suggestion to combine these references.

Indeed, "the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggest the desirability of the combination." See MPEP 2143.01 and also *In Re Mills*, 916 F.2d 680 (Fed. Cir. 1990); "there must be a suggestion or

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motivation in the reference to do so." *Id.* For at least the following reasons, the combination proposed by the Examiner has failed to meet these requisite tests.

Products containing psyllium seed husk are currently widely used for normalizing bowel function and laxation. Psyllium seed husk contains natural mucilage that forms a gelatinous mass on contact with water. Thus, milled psyllium seed husk, with its increased surface area, is known to exhibit poor dispersability and mixability with water, or upon contact with saliva, as the components tend to form an undesirable gel. Known chewable and liquid form of psyllium husk have been used in the past and have resulted in a number of problems and inconvenience to consumers. Thus, a composition containing xylose and arabinose, has been found in accordance with the present invention to result in improved gellation and solves a longfelt need in the art to prevent the problems experienced by consumers in the past.

The Office Action states that Nakamura shows that compositions that comprise xylose and arabinose are well known in the art. Nakamura relates to a rice cooking method wherein a water-soluble hemicellulose is added to rice for improved soaking of rice and for consistency of texture. Nakamura does not teach any desirable ratio of xylose to arabinose, nor does Nakamura teach agglomerates of xylose and arabinose having any specified surrounding layers. The Examiner has merely concluded in the Office Action that a composition comprising xylose and arabinose obviates the use of any composition comprising xylose and arabinose. Applicant submits that the use of a hemicellulose as a source of xylose and arabinose does not obviate the compositions claimed in accordance with the current invention.

In addition, the present invention relates to a polysaccharide component comprising at least one of a first surrounding layer and optionally a second surrounding layer. All of the claims in the present invention relate to a layered composition. The Office Action states that Colliopoulos relates to coated dry blended ingredients. However, Colliopoulos does not teach the use of a first hydrophobic layer and a second hydrophilic layer. As such, respectfully, the Examiner has failed to establish any *prima facie* case of obviousness, because those of ordinary skill, given the disclosures of Marlett, would not have consulted disclosure relating to a rice cooking method (such as those described in Nakamura) and psyllium husk composition (such as those described in Colliopoulos) to create further improvement in the polysaccharide described in Marlett. In particular, given the benefits of the

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polysaccharide fractions described in Marlett, it would not have been expected that the artisan would successfully substitute components described in Nakamura or Colliopoulos with components described in Marlett, since Marlett teaches the removal of those components which contribute to the unpleasant or unsafe qualities of the husk.

The present rejection should therefore be withdrawn on the basis of failure to establish the requisite *prima facie* case.

Moreover, even if a *prima facie* case were established (and Applicants contend that the Examiner has not done so), there would have been no reasonable expectation of success in combining the composition described in Nakamura, including the various excipients described therein, with the polysaccharide fraction described in Marlett. Again, Marlett makes clear that the fractions described therein exhibit dramatic differences in performance, particularly physical property, relative to other disclosed uses of xylose and arabinose containing compositions. As such, there would have been no expectation of success that adoption of the teachings of Nakamura would have been at all useful in combination with the polysaccharide fraction of Marlett. The psyllium husk and the fraction described in accordance with the present invention are, quite simply, materially different, having many different behaviors and properties.

In addition, the Office Action states that claim 24 is rejected under 35 USC §103(a) over Nakamura et al and Marlett et al further in view of Barbera (US Patent No. 5,425,945). Barbera discloses an agglomerated composition of psyllium husk. As discussed above, the composition claimed in the present invention exhibits unexpected properties not otherwise seen in compositions containing psyllium husk. Applicant submits again that there is a demotivation of the ordinarily skilled artisan to rely on literature relating to psyllium husk for the successful optimization of xylose and arabinose polysaccharides fractions based on the inherent problems that have been found with psyllium husk in the past. More particularly, a 100 micron sized psyllium husk could not be substituted in an agglomerate having a 3:1 ratio of xylose and arabinose at a particle size ranging from about 0.001 microns to about 150 microns as claimed in accordance with the present invention. If a substitution were made as discussed above, the inherent problems that exist with psyllium husk would remain. Applicants respectfully assert that this rejection fails for the same reasons as set forth above, namely

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failure to present a *prima facie* case of obviousness. Thus, applicants respectfully traverse the 35 USC § 103 rejection.

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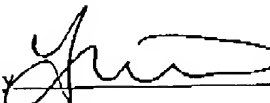
CONCLUSION

In light of the above remarks, it is requested that the Examiner reconsider and withdraw the rejections under 35 USC § 101 and 35 USC § 103. Early and favorable action in this case is respectfully requested.

Applicants have made an earnest effort to place their application in proper form and to distinguish the invention as now claimed from the applied references. In view of the foregoing. Applicants respectfully request reconsideration of this application, and allowance of Claims 1-43.

Respectfully submitted.

Cimiluca et al.

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